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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/399,743	09/20/1999	Karlheinz Druz	9350-0136-0	2655

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EXAMINER

KIM, SUN U

ART UNIT PAPER NUMBER

1723

DATE MAILED: 06/25/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/399,743

Applicant(s)
Druz et al.

Examiner
John Kim

Art Unit
1723



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 22, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) 5-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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1. Applicant's election with traverse of Group I (claims 1-4) in Paper No. 7 is acknowledged. The traversal is on the grounds that Group II-IV are directly dependent from the claims of Group I as such these groups are not separable. This is not found persuasive because the inventions are distinct as described in paragraph 2-4 of the Paper No. 6. If claims of Group I are found allowable, withdrawn process claims of Group II or III will be rejoined.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to **a single paragraph on a separate sheet** within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Correction is required.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe what is the basis of weight that claimed amino acids proportions are based on. Are the weight proportions of amino acids based on total weight of amino acids or are the weight proportions based on total weight of hemodialysis fluid components including weights of amino acids.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite for failing to particularly point out whether the weight proportions of amino acids are based on total weight of amino acids or whether the weight proportions of amino acids are based on total weight of hemodialysis fluid components including weights of amino acids.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over The International Journal of Artificial Organs, Vol. 1, No. 1, 1978, pages 112-113 (hereinafter referred to as Quarto di Palo et al) in view of the admitted prior art (see Table 2 on page 6 of the specification). Quarto de Palo et al teach that amino acids were added to the dialysis solution in a concentration equal to that of normal plasma and treating patients with above concentrations of amino acids in normal plasma resulted in prevention of amino acid loss during hemodialysis, restoration of the pathologically decreased values and removal of the amino acids present in blood in increased concentrations (see page 12). Furthermore, Quarto de Palo et al teach that administering amino acids in the right proportions and at the most favorable time i.e. during dialysis, they expected a greater utilization of amino acids for protein synthesis than for energy purpose (see page 12). Claims 1-4 essentially differ from the dialyzer fluid comprising the claimed amino acid concentrations in its claimed proportions. Specification teaches that the amino acid concentrations occurring in the plasma of a healthy person are set forth in Table 2 of the page 6 of the specification which is the claimed amino acid concentrations in a dialyzer fluid as claimed in claim 4. It would have been obvious to a person of ordinary skill in the art to modify the dialyzer fluid of Quarto di Palo et al to arrive at the claimed proportions of amino acids in the dialyzer fluid with known information of the amino acid concentrations occurring in the plasma of a healthy person to provide the improved advantages in prevention of amino acid loss during hemodialysis, restoration of the pathologically decreased values and removal of the amino acids present in blood in increased concentrations.


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9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,670,176 teaches amino acid solutions for treatment of peritoneal dialysis solution.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
June 20, 2002